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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,445	02/25/2004	Rodney A. Welch	096429-9141	5346

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EXAMINER	
SAIDHA, TEKCHAND	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/786,445	WELCH ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 12-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7.16.04, 7.11.05 &*. 7/17/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election

1. Applicant's election without traverse of Group IV (claims 9-11) in the reply filed on June 13, 2006 is acknowledged.

2. **Claims withdrawn**: Claims 1-8 & 12-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. ***Priority***

Applicant's claim for domestic priority under 35 U.S.C. 119(e), filed 10.26.2000, is acknowledged.

4. Drawings filed on 2/25/2004 is acknowledged and is accepted by the Examiner.

5. ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

6. ***Claim Rejections - 35 USC § 112*** (first paragraph)

Written Description

Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a method of reducing the viscosity of mucin or a glycosylated polypeptide comprising contacting the material with a viscosity reducing effective amount of StcE (secreted protease of C1 esterase inhibitor) polypeptide from any source, the claimed genus.

The disclosure of a single species is rarely, if ever, sufficient to describe a broad genus, particularly when the specification fails to describe the features of that genus, even in passing. (see In re Shokal 113USPQ283(CCPA1957); Purdue Pharma L. P. vs Faulding Inc. 56 USPQ2nd 1481 (CAFC 2000) specification disclosed single variant of SEQ ID NO:1 which encodes for a recombinant human PDEXV enzyme. The possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. See, e.g., Pfaff F. Wells Electronics, Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1 568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991). In claims to genetic material, generic statement such as ''vertebrate insulin CDNA'' or mammalian insulin CDNA,'' without more, is not adequate written description of claimed genus, since it does not distinguish genus from others except by function, and does not specifically define any of genes that fall within its definition, or describe structural features commonly possessed by members of genus that distinguish them from others'; accordingly, naming type of material generally known to exist, in absence of knowledge as to what that material consists of, is not description of that material (Eli Lilly, 119 F.3d at 1568, 43 USPQ2d 130at 1406).

In the instant case, the specification only provides for a method of reducing the viscosity of mucin or a glycosylated polypeptide comprising contacting the material with a viscosity reducing effective amount of StcE (secreted protease of C1 esterase inhibitor) polypeptide of SEQ ID NO: 2 or 19 from *E. coli (single species)*, the disclosed species. No other species are either know in the art or are described in the instant specification. The disclosed species of SEQ ID NO: 2 or 19 as used in the method have not been shown to be representative of the genus claimed.

Therefore, many functionally unrelated StcE polypeptides are encompassed within the scope of these method claims. The specification discloses the application of 2 sequences to be effective in the method of reducing the viscosity of a mucin or glycosylated polypeptide of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus, which is drawn to a method using any StcE polypeptide from any source and for which no structure is apparent. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicants' attention is further directed to "A method patent for treating the side effects of pain relievers which was invalidated for failing to adequately describe the compound used in the claimed method, the U.S. District Court for the Western District of New York rules. Granting a summary judgment motion, the court reasons that the written description requirement of 35 U.S.C. §112 ¶1 cannot be satisfied by merely providing the desired function of the compound without more detail on the

compound's structure, chemical formula, chemical name, or physical properties. The court also stresses the applicability of the written description requirements to the compound used, even though the patent consists of method claims rather than compound claims. *University of Rochester v. G.D. Searle & Co. Inc*. Page 427.

7. ***Enablement Rejection***

Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing the viscosity of mucin or a glycosylated polypeptide comprising contacting the material with a viscosity reducing effective amount of StcE (secreted protease of C1 esterase inhibitor) polypeptide of sequence of SEQ ID NO: 2 or 19, does not reasonably provide enablement for a method of reducing the viscosity of mucin or a glycosylated polypeptide comprising contacting the material with a viscosity reducing effective amount of StcE from any source. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988))[*Ex parte* Forman [230 USPQ 546 (Bd. Pat. App. & Int. 1986)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim. The factors most relevant to this

rejection are [the scope of the claims, unpredictability in the art, the amount of direction or guidance presented, and the amount of experimentation necessary].

The scope of the claims does not commensurate with the enablement provided by the disclosure with regard to the extremely large number of StcE polypeptides broadly encompassed by the claims. While the skills of the artisan in the science of enzymology and recombinant techniques are high, it is not routine in the art to screen for StcE polypeptides from any source, given the guidance of a single StcE polypeptide (a protease) from *Escherichia coli*. The prior art is silent about the occurrence or the existence of such polypeptides from other sources.

The specification does not support the broad scope of the claims which encompass StcE polypeptides from any source because the specification does **not** establish: (A) regions of the protein structure which are conserved among different organisms, plants and animals and which may be obtained from other species without undue experimentation; (B) the general nature and distribution of StcE polypeptides among different species; (C) a rational and predictable scheme with an expectation of obtaining the desired StcE polypeptide(s) from any source having enzymatic or biological function of catalyzing or reducing the viscosity of a mucin or a glycosylated polypeptide; and (D) the specification provides insufficient guidance to methods which are likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a

reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of exact nature of the StcE polypeptides having the desired enzymatic characteristics in order to be successfully employed in the viscosity reducing method is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

8. ***Claim Rejections - 35 USC § 112*** (second paragraph)

Claims 9-11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9, line 3, recites the abbreviation 'StcE'. The first use of an uncommon abbreviation must be spelt out which may be subsequently abbreviated. The claim is unclear about this uncommon abbreviation. It appears that StcE stands for 'secreted protease of C1 esterase inhibitor'. If this is the case, amending the claim accordingly, will overcome this rejection.

Claims 10-11 are included in the rejection for failing to correct the defect present in the base claim(s).

9. ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982);

In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-11 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-5 of copending Application No. 11/294,087 (PG PUB **20060153828**). This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Claims 9-11 in the instant application are identical to claims 1-3 in the copending application, while claims 4-5 in the copending application are obvious variation(s) of claims 1-3 of the instant application.

10. No claim is allowed.

11. During a telephone interview with the Applicants' representative, Jill Fahrlander, on July 27, 2006, allowable subject matters were discussed and Applicants were invited to amend the claims to place them in condition for allowance.

However, the discussion did not result in an agreement being reached hence this Office Action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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